Citation:

Sandora TJ, Taveras EM, Shih MC, Resnick EA, Lee GM, Ross-Degnan D, Goldmann DA. A randomized, controlled trial of a multifaceted intervention including alcohol-based hand sanitizer and hand-hygiene education to reduce illness transmission in the home. *Pediatrics*. 2005 Sep; 116 (3): 587-594.

PubMed ID: 16140697

Study Design:

Cluster randomized controlled trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To determine whether a multifactorial campaign centered on increasing alcohol-based hand sanitizer use and hand-hygiene education reduces illness transmission in the home.

Inclusion Criteria:

- Family had at least one child between six months and five years of age enrolled in out-of-home child care (the oldest child who met these criteria was defined as the index child)
- Index child was enrolled in out-of-home child care with at least five other children for at least 10 hours per week
- Family planned to reside in the area and keep the index child enrolled in the center for the duration of the study
- Family had access to a telephone
- Primary home caregiver could speak English or Spanish
- Household member defined as an individual who spent at least three nights per week in the home.

Exclusion Criteria:

- Families whose homes functioned as family child care centers
- Families with a household member whose occupation included working with children under the age of six for at least 10 hours per week
- Families who reported using alcohol-based hand sanitizer in the home at least once a day.

Description of Study Protocol:

Recruitment

- Families were recruited from November 2002 to April 2003. Recruitment was based on attendance of children to 26 specific child care centers in three Massachusetts neighborhoods: Boston, Brookline and Cambridge
- The director of each child care center was contacted by telephone and gave permission to recruit families who were enrolled at the center. An initial recruitment letter was distributed through the child care center to all families
- Families chose to provide contact information for eligibility screening or decline participation
- All interested families were screened by telephone for study eligibility.

Design

Cluster, randomized controlled trial (child care center as unit of randomization).

Blinding Used

Computer generated randomization assignments; study investigators did not know until they enrolled families of the center's randomization status, but subjects and data collectors were not blinded.

Intervention

- Families in the treatment group received a supply of hand-sanitizer (Purell) to use in the home for five months and bi-weekly hand-hygiene educational materials at home for five months (e.g., engaging fact sheets and tips and toys designed to serve as triggers for awareness)
- Families in the control group did not receive hand sanitizer but did receive biweekly education about a healthy diet; families were asked not to use hand sanitizer during the five months.

Statistical Analysis

- Analyses were intent-to-treat
- Baseline demographic characteristics between groups were compared using Fisher's exact test for categorical variables and Wilcoxon rank sum test for continuous variables
- A Poisson distribution modeled the number of secondary illnesses in each family
- Generalized estimating equations were used to compare transmission rates between groups, accounting for correlations between families within a child care center; demographic variables were used for adjustments
- Pre-planned secondary analysis compared secondary illness rates stratified by sanitizer use and used the same covariates as the primary analysis.

Data Collection Summary:

Timing of Measurements

- Caregivers were mailed a survey at the beginning to ask about family demographics and knowledge and practices regarding hand hygiene and illness transmission (adapted from a standardized instrument used in previous studies); repeated at five months

- Families received a symptom diary to record the timing and duration of illness among family members; caregivers were contacted by telephone biweekly to elicit reports of symptoms of respiratory and GI illnesses in the family during the preceding two weeks and the use of hand sanitizer and adverse reactions to the product in last two weeks.

Dependent Variables

- Overall rates of secondary-respiratory illness (defined as the number of secondary illnesses per susceptible person-month)
- Overall rates of secondary-GI illness (defined as the number of secondary illnesses per susceptible person-month)
    - An illness was defined as a secondary case when it began two to seven days after the onset of the same illness type (respiratory or GI) in another household member
        - Respiratory illness defined as the following symptoms for one day or one of these symptoms for two consecutive days: Runny nose; stuffy or blocked nose or noisy breathing; cough; fever, feels hot or has chills; sore throat and sneezing
        - GI illness defined as either or both of the following symptoms: Watery or loose bowel movements; vomiting
- Primary illness incidence rates, calculated by dividing the number of primary illnesses by the number of person-months at risk for acquiring a primary illness
    - An illness was defined as new or separate when a period of at least two symptom-free days had elapsed since the previous illness.

Independent Variables

Intervention or control groups.

Control Variables

- Number of children age zero to five in household
- Household income
- Race
- Primary caregiver occupation and education level
- Previous experience using hand sanitizers
- Term to adjust for reported hand-hygiene practices in the home at baseline: Score derived from responses to respiratory and GI-specific hand-hygiene items on the baseline survey (length of time to perform routine handwashing, changes in handwashing practices during times of illness, and frequency of handwashing in relation to specific events associated with a high likelihood of illness transmission).

Description of Actual Data Sample:

- *Initial N:*
    - 647 families received initial letters about the study
    - 429 provided contact information
    - 358 were eligible for enrollment
    - 292 families were randomly assigned (82% of those eligible; 66 families did not return consent)
- *Attrition (final N):* As above, all assigned families included in the intent-to-treat analysis
    - Most common reasons for 71 ineligible: Current use of sanitizer in the home (N=17); no children aged six months to five years in child care for at least 10 hours per week

(N=15); family member working with children under six (N=15) and family moving before end of study (N=8)
    - Treatment group: 155 families from 14 child care centers; 12 withdrew before the end and three families lost to follow-up
    - Control group: 137 families from 12 child care centers; 11 withdrew before the end and eight were lost to follow-up
    - Proportion of families completing the study did not differ between groups (P=0.28).
- *Age:* Age of index child was about three years; age of caregiver was about 36-37 years
- *Ethnicity:* 79% were white; about 6% were Hispanic
- *Other relevant demographics:*
    - 91% of caregivers had at least a college degree
    - 70% families had an annual household income of at least $80,000
- *Anthropometrics:*
    - Baseline demographics did not differ between groups
    - Participants were generally healthy. The most common underlying illness was asthma (7% of participants); same in both groups
- *Location:* Boston, Brookline and Cambridge, Massachusetts.

Summary of Results:

Key Findings

- The secondary GI illness rate was significantly lower in intervention families compared with control families (incidence rate ratio: 0.41, 95% CI: 0.19-0.90)
- The overall rate of secondary respiratory illness was not significantly different between groups (incidence rate ratio: 0.97, 95% CI: 0.72-1.30)
- However, families with higher sanitizer usage had a marginally lower secondary respiratory illness rate than those with less usage (incidence rate ratio: 0.81, 95% CI: 0.65-1.09).

Variables	Treatment Group Measures and Confidence Intervals	Control Group Measures and Confidence Intervals	Statistical Significance of Group Difference
Total number of illnesses	GI: 135 Respiratory: 974	GI: 117 Respiratory: 828	NS
Number of families contributing illnesses	GI: 78 Respiratory: 140	GI: 60 Respiratory: 118	NS
Total number of person-days for observation	GI: 69, 118 Respiratory: 69, 118	GI: 60, 413 Respiratory: 60, 413	--
Total illness incidence rate	GI: 0.06 Respiratory: 0.43	GI: 0.06 Respiratory: 0.42	NS
Number of primary illnesses	GI: 125 Respiratory: 733	GI: 99 Respiratory 626	NS
Primary illness rate	GI: 0.06 Respiratory 0.37	GI: 0.05 Respiratory 0.37	NS

Number of secondary illnesses	GI: 10 Respiratory: 241	GI: 18 Respiratory: 202	--
Secondary illness rate	GI: 0.17 Respiratory: 0.72	GI: 0.35 Respiratory: 0.72	Significant for GI only: P=0.03, 95% CI 0.19-0.90

Other Findings

- A total of 1,802 respiratory illnesses occurred during the study, 443 (25%) were secondary illnesses
- A total of 252 GI illnesses occurred during the study, 28 (11%) were secondary illnesses
- Primary caregivers reported using hand sanitizer a median of 5.2 times per day in intervention families
    - 55 families (38%) used at least two ounces of sanitizer in a two-week period (about 60 pushes or about four to five uses per day)
    - When compared to families who used less sanitizer, secondary respiratory illness for those who used the larger amount of hand sanitizer was 0.81 compared with those who used the smaller amount (95% CI: 0.65-1.09, P=0.06); the same trend was not observed for GI illness
- There were no differences for seasonality
- 45 families reported 112 adverse events related to hand sanitizer use in 7% of the phone calls; they included dry skin (63%), irritation (18%), stinging (10%), smells bad (6%), dislike it (2%), allergic reaction (2%) and too slippery (1%).

Author Conclusion:

- A multifactorial intervention emphasizing alcohol-based hand sanitizer use in the home reduced transmission of GI illnesses within families with children in child care
- Hand sanitizers and multifaceted educational messages may have a role in improving hand-hygiene practices within the home setting.

Reviewer Comments:

Strengths

- *Handwashing practices, other behaviors, and demographics similar across groups*
- *Power analysis was performed prior to start of the study*
- *Randomized controlled trial*
- *Use of many important covariates.*

Limitations

- *Self-reported illness without microbiological confirmation*
- *No placebo*
- *No direct observation of hand sanitizer; it is possible that families overreported the amount of sanitizer used to conform to social expectations*
- *Low participation rates*
- *Homogenous sample of largely white, high income, high education subjects limits generalizability*

- *Lack of blinding for subjects and data collectors.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes
Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	No
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	No
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes

3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	No
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	No
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes

6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	???
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes

8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	Yes
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	No
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	No